12. (Amended) A method for [inhibiting, treating, or] reducing [unwanted a] hypersensitivity side effects caused by a pharmaceutical composition [including a drug or active agent and] containing [a carrier containing] amphiphilic molecules[, said method] comprising [employing a] administering an effective amount of complement activation inhibitor to a subject in conjunction with the administration of said pharmaceutical composition.

13. (Amended) The method according to claim 12 wherein said amphiphilic molecule is polyethoxylated oil or a derivative thereof.

14. (Amended) The method according to claim 12 wherein said carrier is selected from the group consisting of liposomes, colloidal dispersions, particulate biomaterials, radiocontrast agents and emulsifiers[-base drug vehicles].

15. (Amended) The method according to claim 12 wherein said [drug is selected from the group consisting of] pharmaceutical composition includes as an active ingredient antifungal[, and] or anticancer drugs.

16. (Amended) The method according to claim 15 wherein said drug is doxorubicin, daunorubicin[,] or amphoterin B.

17. (Amended) The method according to claim 12 wherein [said] the pharmaceutical composition includes as an active agent [is selected from the group consisting of] hemoglobin[, and] or polynucleotides.

REMARKS

Reconsideration is respectfully requested in light of the foregoing amendments and following remarks. Entry of the amendment is respectfully requested since it would reduce the issues on appeal and does not introduce new matter.

Claims 1-4 and 6-9 are pending.

Claims 1, 6 and 7 are amended. Claim 1 has been amended to address points raised in the Official Action and to correct an obvious error. Claims 6 and 7 were also amended to address a point raised in the Official Action. Support for the enhancement amount was derived from Table 6 by simple calculation. The numbers, existing in the table, were used to determine the magnitude of the enhancement. No new matter is believed to have been introduced.

Rejections under 35 USC 112, Second Paragraph

Claims 1-6, 10 and 12-17 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out distinctly claim containing subject matter which applicant regards as his invention. Applicant respectfully traverses.

Claims 1, 5, 6, 10, 12 and 14 have been amended to address the points raised in the Official Action which should render the rejection as stated moot.

With regard to claim 4, please note page 20 at lines 20-31 where Cremophor (generic term) and Cremophor EL ("species") are defined. Both these terms have art established meanings.

Withdrawal of the rejection is respectfully requested.

Rejections under 35 USC 103

Claims 1-6, 10 and 12-17 are rejected under 35 USC 103 as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharrier (5,744,156). Applicant respectfully traverses.

The claims have been amended to more clearly the inventive contribution- the reduction of hypersensitivity, due to complement activation by the presence of an amphiphilic material, e.g. a polyethoxylate containing material, in a pharmaceutical composition material, by the administration of an effective amount of an inhibitor of complement activation inhibitor.

There is no recognition in either the primary or secondary reference of the problem discovered and solved by Applicants.

Ko teaches chimeric molecules composed of a first and second polypeptides, both of which inhibit complement activation. The chimeric proteins are taught to reduce inflammation. Conditions mentioned include those associated with ischemia-reperfusion, crash injury, burns, ARDS, autoimmune disorders, hyperaccute rejection of grafts, etc..

De Lacharriere teaches the use of a substance P antagonist for the preparation of a pharmaceutical composition for treating skin reddening of a neurological origin. There is no mention of hypersensitivity associated with complement activation by amphiphilic molecules nor its treatment in the manner claimed.

The teaching of references, taken alone or in combination, are insufficient to suggest the claimed invention.

Further, it is respectfully submitted that the references fail to suggest their combination. There is no problem evident in one for which the other is a solution.

Since a prima facie case has not been established, withdrawal of the rejection is respectfully requested.

In light of these is, it is submitted that a proper *prima facie* case has not been established and the rejection withdrawn. This is respectfully requested.

Conclusion

Having addressed all the rejections and objections, allowance of the application is believed to be in order. A notice to this effect is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 210-380** referencing docket no. WRAIR 97-18 (378332000900). However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: January 8, 2001 By: _____

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